MAY 2 2 2013

5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:

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Contact Person:

Michael Browne
Quality and Regulatory Affairs Manager
Advanced Medical Solutions (Plymouth) Ltd

Date of Summary: 20th May 2013

Device Trade Name: Barle Tissue Adhesive

Product Codes: MPN

Common or Usual Name: Topical Skin Adhesive

Classification Name: Tissue Adhesive (21 CFR 878.4010)

Predicate Device(s):

LiquiBand® Ultima (K100284)
Dermabond Nx (K100423)
Dermabond (P960052)
SurgiSeal (K082993)
Derma+Flex QS (K101276)

Device Description:

Barle Tissue Adhesive is a sterile, topical tissue adhesive containing 2-octyl cyanoacrylate for wound closure. Barle Tissue Adhesive is supplied in a single patient use configuration. The applicator is composed of a crushable glass ampoule contained within a plastic polypropylene applicator. The ampoule is crushed through force applied by the clinician to the 'wings' of the applicator body. It is applied to easily approximated skin edges and polymerizes within minutes. The device is contained within a PET/tyvek blister.

Indication for Use:

Barle Tissue Adhesive topical skin adhesive is intended for topical applications only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma induced lacerations. Barle Tissue Adhesive topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Technological Characteristics

The technological characteristics of Barle Tissue Adhesive are substantially equivalent to the predicate devices.

Barle Tissue Adhesive consists of a liquid topical skin adhesive formulation packaged within a dispensing applicator. The device is supplied in a sterile single use package for use in wound closure procedures. Barle Tissue Adhesive design allows for precise application of the adhesive to the wound area. The topical skin adhesive is designed to bond to the skin to provide wound closure maintaining wound approximation.

The main differences between Barle Tissue Adhesive and the LiquiBand Ultima predicate are

1 – change in formulation from n-butyl cyanoacrylate to 2-octyl cyanoacrylate

2 – Modifications to the LiquiBand® Ultima applicator design to use only one tip

Substantial Equivalence:

Barle Tissue Adhesive is substantially equivalent to Dermabond Nx (K100423) with regard to Indication For Use, formulation, technology, target population, intended application, mechanism of action and performance at achieving its intended use and LiquiBand Ultima Topical Skin Adhesive (K100284) with regard to Indication For Use, applicator technology, target population, intended application, mechanism of action and performance at achieving its intended use.

Biocompatibility

The biological evaluation of Barle Tissue Adhesive has been performed in accordance with ISO 10993 and the FDA-modified 'Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing, for breached or compromised surface with blood contact for the wound closure and subsequent layer adhesives' and the Special Controls document 'Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin' May 30th 2008

The biocompatibility tests were conducted for a "breached or compromised surface with blood contact device with prolonged contact duration of greater than 24 hours but less than 30 days" since the adhesive is applied to a wound and allowed to dry. All of the testing was performed in accordance with ISO 10993 and using Good Laboratory Practices (GLP).

The results provide evidence that Barle Tissue Adhesive is safe and biocompatible for its intended use and therefore substantially equivalent to the predicate devices.

Sterilisation and Shelf Life

Sterilisation of Barle Tissue Adhesive is the same as the predicate LiquiBand® Ultima (K100284). Sterilisation is carried out to a SAL 10^{-6} by dry heat for the adhesive and ethylene oxide for the applicator and packaging.

Real time and accelerated stability testing data has been generated to support this submission.

Substantial Equivalence Testing Summary:

The following comparative testing demonstrated substantially equivalent performance between Barle Tissue Adhesive, Dermabond Nx and LiquiBand Ultima,:

- Tensile strength (ASTM F2255-05, F2258-05, F2458-05, F2256-05)
- Degradation by hydrolysis
- Heat of polymerization
- Ease of actuation
- Polymerization setting time
- Purity analysis
- Moisture content
- Porcine wound healing
- Biocompatibility testing; cytotoxicity, irritation, sensitization, acute dermal toxicity and intramuscular implantation

Conclusion

Based on the nonclinical testing carried out Barle Tissue Adhesive is considered as safe, as effective and performs as well or better than the legally marketed predicate devices – Dermabond Nx and LiquiBand Ultima.

Barle Tissue Adhesive was evaluated in tests to establish a performance and safety profile in accordance with the Class II Special Controls Guidance Document: Tissue Adhesive for Topical Approximation of Skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Advanced Medical Solutions (Plymouth) Ltd.
% Mr. Michael Browne
Western Wood Way
Langage Science Park
Plymouth, Devon
United Kingdom PL7 5BG

May 22, 2013

Re: K123133
Trade/Device Name: Barle Tissue Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: April 25, 2013
Received: May 02, 2013

Dear Mr. Browne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: K123133

Device Name: Barle Tissue Adhesive

Model Number: 000-579

Indications For Use: Barle Tissue Adhesive topical skin adhesive is intended for topical applications only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma induced lacerations. Barle Tissue Adhesive topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Prescription Use: **YES** AND/OR Over-the-Counter Use: **NO**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123133